

REMARKS

The Office Action has objected to Claims 58 and 66. In addition, it has rejected Claims 58-73 and 75 under 35 U.S.C. §103(a) as defining subject matter which is allegedly rendered obvious by the teachings in WO 99/59426 to which Heikkila et al. are inventors (“Heikkila et al. I”) in view of the teachings in U.S. Patent No. 5,017,400 to Olinger et al. (“Olinger et al.”). Further Claims 58-73 and 75 are rejected as defining subject matter which is rendered obvious by the teachings in WO 99/47532 to which Heikkila et al. (“Heikkila et al. II”) are listed as inventors in view of the teachings in WO 91/07100 in which the inventors are Oravainen et al. (“Oravainen et al.”).

Applicants have amended and added claims, which, when considered with the comments hereinbelow are deemed to place the present case in condition for allowance. Favorable action is respectfully requested.

At the outset, before addressing the issues raised in the Office Action, it is to be noted that applicants have cancelled Claims 58-73 without prejudice. Applicants have not abandoned the subject matter therein and reserve the right to file a continuation application directed thereto.

In addition, applicants have amended Claim 75. In particular, step (c) has been amended to recite that the microcrystallized particles are conditioned at a temperature of 40-90 °C, as described on Page 17, Lines 7-9 of the instant specification. In addition, step (c) has been amended to recite that the composition produced is a eutectic mixture containing from 50% to 75% by weight xylitol and from 25% to 50% by weight maltitol. Support is found in Examples 1 and 3 and original Claim 4 of the instant specification.

Claims 76-90 have been added to the application. Support for Claim 76 is found on Page 13, Line 26 to Page 14, Line 7 and Page 15, Lines 5-8 of the instant specification. Support for Claims 77-85 is found in original Claims 21-29 of the instant specification. Support for Claim 86 is found on Page 10, Lines 1-6 of the instant specification. Claims 87 and 88 are supported by the disclosures found on Page 17, Lines 7-9, while support for Claims 89-90 is found on Page 17, Lines 29-31 of the instant specification.

No new matter is added to the application.

The present invention is directed, inter alia, to a process for the microcrystallization of polyols into a polyol composition, comprising the steps of:

(a) spraying a liquid feed of dissolved xylitol and maltitol containing at least 25% by weight of each at the dry solids concentration of 60-90% into contact with a gas suspended dry feed of small crystals containing xylitol and maltitol so as to wet the surface of said dry feed particles with said liquid feed, wherein the ratio of liquid feed to dry feed is between 2:1 and 1:4;

(b) evaporating the solvent of said liquid feed causing microcrystallization of said dissolved xylitol and maltitol on said dry feed particles and drying in the gas suspended state to a free moisture content of 0.5 – 3%; and

(c) conditioning the microcrystallized particles at a temperature of 40-90°C to provide a solid randomly agglomerated microcrystalline xylitol-maltitol composition with microcrystals of 5- 10 micrometers in size and a free moisture content of 0.05% - 0.5% and melts at about 90 °C,

wherein the ratio of xylitol and maltitol in said feeds being such that the resulting microcrystalline eutectic mixture contains from 50% to 75% by weight of xylitol and from 25% to 50% by weight maltitol; and

(d) optionally milling the dried randomly agglomerated microcrystalline polyol composition from step c) to a mean particle size of 0.1 – 0.4 mm.

Pursuant to the rejection of Claims 58-73 and 75 under 35 U.S.C. §103(a), the Office Action cites Heikkila et al. I and Olinger et al.

Heikkila et al. I disclose a process for the crystallization of xylitol with gas suspended from solid particles containing microcrystalline xylitol, causing substantial removal of the solvent component of said liquid and allowing the resulting xylitol material to form an essentially solid composition of matter comprising a multitude of microcrystals of xylitol, and causing said xylitol composition to be conditioned during a further drying step to provide a product consisting essentially throughout its entire structure of a multitude of microcrystals of xylitol agglomerated together in a random manner.

Olinger et al relate to edible compositions containing a sweetener combination of xylitol and maltitol. Unlike the present invention, the xylitol and maltitol are considered separate ingredients; and are not prepared together, as taught in Olinger et al.

Olinger et al. disclose a mixture of discrete crystals of maltitol and xylitol that are separately made and mixed together. There is no teaching or suggestion in Olinger et al. that would guide a person skilled in the art to even look for an option to try to crystallize xylitol and maltitol together.

Although Olinger et al. show the desirability of a mixture of crystals of xylitol and maltitol, neither Olinger et al. nor Heikkila et al. I provide any reason to combine crystals of xylitol and maltitol in a microcrystallization process. In the usual methods of preparation of compositions of the type described, the xylitol and maltitol are stored and handled as separate

ingredients. Their combination occurs when they are mixed together with the other ingredients of the edible combination being prepared.

Applicants respectfully submit that Heikkila et al. I and Olinger et al. are not combinable in the first instance, since there is no motivation to combine the two references in the way that the Office Action has done. Heikkila et al. I relate to the novel process of preparing a product comprising microcrystalline xylitol. The whole thrust of the teaching therein relates to the process for the crystallization of xylitol. There is no teaching therein of a process for preparing any product by microcrystallizing together xylitol and maltitol or for a product made therefrom.

Olinger refers to a mixture of crystals—not microcrystals of xylitol and maltitol. It does not teach, disclose or suggest any microcrystalline product—let alone a mixture of microcrystalline product. Although Olinger, et al. contain a mixture of crystals of xylitol and maltitol, it does not provide any motivation to prepare a mixture of microcrystals of xylitol and maltitol. Olinger et al. disclose a mixture of discrete crystals of xylitol and maltitol that are separately made and mixed together. As described, the xylitol and maltitol are individually added to the composition. As taught by Olinger et al., the combination of polyols were made by mixing pure crystals of separate polyols. At the time of the filing of the above-identified application, maltitol and xylitol required very high purity of their aqueous solutions for satisfactory conventional crystallizations. Based on the teachings in the references, there would be no reason to make a mixture of microcrystalline xylitol and maltitol.

The Office Action refers to the passage on Page 5, Lines 21-26 of Heikkila et al. I which states the microcrystalline xylitol may be microcrystallized with other compounds;

however, this teaching must be put into perspective of the previous paragraph of Heikkila et al.
on Page 5, Lines 17-20 thereof

The microcrystalline xylitol of the present invention is preferably produced in a pure xylitol form, i.e., containing throughout essentially only xylitol. Thus, the present solid, xylitol product can be produced totally without separate binder which is contrary to the product granulated according to U.S. Patent No. 5,204,115 with a binder.

This passage, taken together with discussions on Page 5, Line2 21-26 of Heikkila et al., indicates that although the microcrystallization of xylitol can be effected in the presence of other compounds, the amount of the other compounds should be low. This passage does not teach, disclose or suggest that the amount of an impurity, such as maltitol ,would be as high as 25% by weight, as claimed. Moreover, one of ordinary skill in the art at the time of the filing of the present application, would not contemplate microcrystallizing two compounds together, when the second compound is present in quantities greater than a few percent. As it would be expected that amounts more of same will significantly and adversely interfere with the microcrystallization and/or weaken the resulting crystalline structure.

Further, it is respectfully submitted that when combined, the teachings of Olinger and Heikkila would, at most, suggest to one of ordinary skill the crystallization of maltitol and the separate microcrystallization of xylitol, utilizing the methodology of Heikkila et al. I. and the product comprised of microcrystals of xylitol and crystals of maltitol. Even assuming that a product contained microcrystals of xylitol and mylitol, this would lead to a different product than that of the claimed process. Even though in some situations the microcrystalline nature of the polyol composition may be lost during the end use, for instance, by dissolving in a dough or melting in a candy, the present polyol composition offers the advantage of providing an intimate

mixture of two desirable non-cariogenic sweeteners. The product produced according to the claimed process is a non-segregating pre-mixture which is much easier to use than having to mix different polyols for each recipe. In addition, it is quite apparent that the use of one process is more efficient rather than two processes, which is needed if xylitol and maltitol are crystallized separately.

A further advantage of the present invention is that the microcrystals of a substantially equimolar mixture of maltitol and xylitol surprisingly form an eutectic mixture having a single melting point different from that of the individual polyols. Thus, maltitol melts in the eutectic mixture with xylitol already at about 90°C (the normal m.p. of maltitol is 148-151°C). One of ordinary skill in the art would not have expected the formation of such an eutectic mixture. This allows use of molten maltitol at a significantly lower temperature than without the eutectic mixture. The lower temperature may be utilized in hard candies, in melt granulation and in contact with any such ingredients which are heat sensitive and which cannot be subjected to higher melting point of pure maltitol. The composition also has a lower melting enthalpy than the combined value for crystalline xylitol and maltitol.

Thus, for the reasons given, this rejection is obviated, and withdrawal thereof is respectfully requested.

Pursuant to the second rejection of the claims under 35 U.S.C. §103, the Office Action cites Heikkila et al. II in view of Oravainen et al.

Heikkila et al. II relate to a process for the crystallization of lactitol. More specifically, Heikkila et al. II disclose a process for the crystallization of lactitol, to a particulate crystalline lactitol product having novel properties, to the use thereof as in foodstuffs, pharmaceuticals and oral hygiene products, as well as to special lactitol sweeteners. The process

comprises: contacting a liquid containing dissolved lactitol with gas suspended fine solid particles containing microcrystalline lactitol; causing substantial removal of the solvent component of said liquid and allowing the resulting lactitol material to form an essentially solid composition of matter comprising a multitude of microcrystals of lactitol; and causing said lactitol composition to be conditioned during a further step to provide a product consisting essentially throughout its entire structure of a multitude of microcrystals of lactitol agglomerated together in a random manner. The invention provides a crystalline lactitol product consisting essentially throughout its entire structure of a multitude of microcrystals of lactitol agglomerated together in a random manner. Oravainen et al teach a hard candy containing 30% to 70% by weight xylitol in combination with 70-30% by weight of sorbitol, maltitol, isomalt, lactitol or mixture thereof. Thus, the combination would suggest a hard candy comprised of lactitol and xylitol and a process for preparing the same. Although Heikkila et al II relate to the process for the microcrystallization of lactitol, as claimed, independent Claims 75 *et seq.* relate to the co-microcrystallization of xylitol and maltitol. Thus, the combination does not teach, disclose or suggest the process of making a composition of preparing microcrystalline xylitol and maltitol by microcrystallizing maltitol and xylitol together. Thus, this rejection is rendered moot. Therefore, this rejection is obviated. Withdrawal thereof is respectfully requested.

Thus, in view of the amendment to the claims and remarks herein, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mark J. Cohen". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

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